UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte NEIL H. BANDER

Appeal No. 2006-0633[1]
Application No. 09/357,709

ON BRIEF[2]

Before SCHEINER, MILLS and GRIMES, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves a method of detecting normal, benign hyperplastic, or cancerous prostate cells in a human subject, by administering labeled antibodies that bind prostate specific membrane antigen (PSMA). The examiner has rejected claims requiring a particular subgenus of anti-PSMA antibodies as lacking adequate written descriptive support. We have jurisdiction under 35 U.S.C. § 134. We will reverse this rejection because we find that appellant's disclosure conveys with reasonable clarity to those skilled in the art that, as of the filing date, appellant was in possession of the claimed invention.

[1] This appeal is related to appeals in related application nos. 09/929,546 (appeal no. 2006-0352), 09/357,710 (appeal no. 2006-1520) and 09/929,665 (appeal no. 2006-0632). We have considered these appeals together.

[2] Appellant requested an oral hearing in this case, however, after reviewing the case, we have determined that an oral hearing will not be necessary and have rendered a decision based on the record. See 37 CFR §§ 41.47(a),(f).

BACKGROUND

"PSMA is an integral membrane protein known to have a short intracellular tail and a long extracellular domain." Specification, page 9. Various researchers have reported that "PSMA is prostate-specific and shows increased expression levels in metastatic sites and in hormone-refractory states" (id., page 8); that "PSMA is more strongly expressed in prostate cancer cells relative to cells from the normal prostate or from a prostate with benign hyperplasia" (id.); and that "PSMA is not found in serum" (id.). According to appellant, PSMA is "an attractive target for antibody mediated . . . imaging and therapy of prostate cancer" (id.). However, "antibody molecules do not, under normal circumstances, cross the cell membrane unless they bind to the extracellular portion of a molecule and become translocated intracellularly," thus antibodies that bind the intracellular portion of PSMA "do[ ] not have access to [the] antigenic target site in . . . viable cell[s]" and will only bind cells that are already dead (id., page 9).

The present invention is directed to methods of detecting normal, benign hyperplastic, or cancerous prostate cells using "biological agents," in this case, polyclonal or monoclonal antibodies which bind the extracellular domain of PSMA. Appellant describes four "particularly preferred" biological agents, monoclonal antibodies E99, J415, J533 and J591, to be "used alone or as a component in a mixture with other antibodies or other biological agents" (Specification, page 19). "In a particularly preferred embodiment . . . a first biological agent is conjugated with a prodrug . . . [and] [t]he prodrug activator is conjugated with a second biological agent . . . preferably one which binds to a non-competing site" on PSMA. "Whether two

biological agents bind to competing or non-competing binding sites can be determined by conventional competitive binding assays" (id., page 27). For example, "[a] competition study was carried out to determine whether J591, J533, E99, and J415 detected the same or different antigenic sites (epitopes) of [PSMA]" (id., page 37). "The results indicated that J591, J533, and E99 each interfere, compete, or block binding of one another but do not block binding of J415 and vice versa" (id., page 38).

DISCUSSION

According to the examiner, "the specification [ ] provides a written description and indicates possession of a genus of antibodies that bind to the extracellular domain of PSMA and four species of such monoclonal antibodies, or species of the genus, e.g. E99, J591, J415, or J533[,]" but does not provide descriptive support for "a subgenus of antibodies that 'compete for binding' to E99, J591, J415, or J533" (Answer, pages 3-4). Consequently, the examiner has rejected claims 68-77, 79-81, 107, 111, 116-128 and 130-152[3] under the first paragraph of 35 U.S.C. § 112.

Claim 68 is representative of the subject matter on appeal:

68. A method of detecting normal, benign hyperplastic, or cancerous prostate cells in a human subject, comprising:
providing an antibody or antigen binding portion thereof which competes for binding to prostate specific membrane antigen (PSMA) with a monoclonal antibody selected from the group consisting of an E99, a J415, a J533, and a J591 monoclonal antibody, wherein the antibody or antigen binding portion thereof is bound to a label effective to permit detection of normal, benign hyperplastic, or cancerous prostate cells;
administering the antibody or antigen binding portion thereof to the human subject; and
detecting the presence of the normal, benign hyperplastic, or cancerous prostate cells by detecting the label.

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[3] Claims 68-77, 79-81, 107, 111, 116-128 and 103-152 are the only claims remaining in the application, claims 1-67, 78, 82-106, 108-110, 112-115, 129 and 153-162 having been previously canceled.

Essentially, the examiner's position is that "antibodies that 'compete for binding' to E99, J591, J415, and J533 . . . constitute a separate subgenus" that was not expressly "recite[d] or reasonably contemplate[d]" in the specification as originally filed (Answer, page 4). Further, the examiner asserts that the only relevant example in the specification "reinforce[s] the idea that 'non-competing' antibodies are [ ] preferred" (id., page 8).

"The 'written description' requirement serves a teaching function, . . . in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'" University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 922, 69 USPQ2d 1886, 1891 (Fed. Cir. 2004) (citation omitted). Another "purpose of the 'written description' requirement is . . . [to] convey with reasonable clarity to those skilled in the art that, as of the filing date [ ], [the applicant] was in possession of the invention." Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). See also Enzo Biochem Inc. v. Gen-Probe Inc., 296 F.3d 1316, 1329, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). The requirement is satisfied when the specification "set[s] forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed." University of Rochester, 358 F.3d at 928, 69 USPQ2d at 1896. Whether or not a specification satisfies the requirement is a question of fact, which must be resolved on a case-by-case basis (Vas-Cath, 935 F.2d at 1562-63, 19 USPQ2d at 1116).

Much has been said on both sides of this issue, but we agree with appellant that the specification describes the disputed subgenus of antibodies, and that this "is not a close case" (Reply Brief, page 1). The specification describes a "method [which]

involves providing a biological agent which binds to an extracellular domain of prostate specific membrane antigen" (Specification, page 10). "Preferred biological agents for use in the method of detecting . . . are antibodies or binding portions thereof, probes or ligands" (id., page 11). The specification further describes four "particularly preferred" monoclonal antibodies which bind the extracellular domain of PSMA (id., page 19). Three of the antibodies, J591, J533, and E99, "interfere, compete, or block binding of one another" to the same epitope on PSMA, but "do not block binding of [the fourth antibody,] J415[,] and vice versa" (id., page 38). Moreover, the specification teaches that "[s]uitable probes or ligands are molecules which bind to the . . . antigens identified by the monoclonal antibodies of the present invention" (id., page 19), i.e., molecules which bind to the same epitopes identified by J591, J533, E99 and J415.

Thus, the specification explicitly describes both competing and non-competing antibodies, and also teaches that other biological agents that bind, or recognize, the same sites identified by J591, J533, E99 and J415 are suitable for use in the claimed method. While it is true that the specification does not explicitly state that other antibodies are included among suitable "molecules which bind to the . . . antigens identified by the monoclonal antibodies of the present invention," we conclude that appellant's disclosure as a whole reasonably conveys to one of skill in the art that appellant was in possession of a method using an antibody "which competes for binding to prostate specific membrane antigen [ ] with a monoclonal antibody selected from the group consisting of an E99, a J415, a J533 and a J591 monoclonal antibody" (claim 68), as of the filing date of this application.

The rejection of claims 68-77, 79-81, 107, 111, 116-128 and 130-152 under the first paragraph of 35 U.S.C. § 112 is reversed.

REVERSED

Toni R. Scheiner
Administrative Patent Judge

Demetra J. Mills
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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